

In re Application of: Andy Wolff et al  
Serial No.: 10/668,274  
Filed: September 24, 2006  
Office Action Mailing Date: December 29, 2006

Examiner: Elizabeth Macneill  
Group Art Unit: 3767  
Attorney Docket: 26486

### **REMARKS**

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-110 are in this Application. Claims 1-4, 18, 20-23, 25-31, 45, 47-50, 52-63, 65-67, 81-91, 93-95, 109 and 110 have been rejected under 35 U.S.C. § 102. Claims 5-16, 17, 19, 32-43, 44, 46, 64, 68-79, 80, 92, 96-107, 108 have been rejected under 35 U.S.C. § 103. Claims 24 and 51 have been canceled in a previous response. Claims 19, 21-24, 46, 48-51, 56, 60, 64, 84, 88, 92 have been canceled herewith. Claims 1, 27, 28, 54, 55, 83 have been amended herewith.

### **Amendments to the Claims**

Independent claim 1 has been amended to incorporate limitations from dependent claims 21 and 22. Consequently, claims 21 and 22 have been canceled. Claim 27, formerly dependent from claim 22, has been amended to depend from claim 1.

Independent claim 28 has been amended to incorporate limitations from dependent claims 48 and 49. Consequently, claims 48 and 49 have been canceled. Claim 54, formerly dependent from claim 49, has been amended to depend from claim 28.

Independent claim 55 has been amended to incorporate limitations from dependent claim 56. Consequently, claim 56 has been canceled.

Independent claim 83 has been amended to incorporate limitations from dependent claims 84. Consequently, claim 84 has been canceled.

In addition, dependent claims 19, 23, 46, 50, 60, 64, 88 and 92 have been canceled, without prejudice.

### **Claim Rejections – 35 USC § 102(b) – Sakuma et al.**

Claims 1-4, 18, 20-23, 25-31, 45, 47-50, 52-63, 65-67, 81-91, 93-95, 109 and 110 have been rejected under 35 USC 102(b) as anticipated by Sakuma et al. (US 5,584,688).

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The Examiner's rejections are respectfully traversed. Yet, in order to expedite prosecution, independent claims 1, 28, 55, and 83 have been amended, to better distinguish them over the cited art.

Claim 1 now recites (added limitation underlined):

"An oral device for controlled drug release, comprising:

a reservoir containing a drug;

an electronic drug release mechanism, for providing said controlled drug release; and

an oral anchoring element, for configuring the oral device for insertion to an oral cavity of a subject, wherein said oral anchoring element is a dental implement, selected from the group consisting of a dental bridge, partial dentures, full dentures, braces, a molar band, a night guard, and a mouth guard". Independent claims 28, 55, and 83 have been similarly limited.

Such anchoring elements as now included in independent claims 1, 28, 55, and 83 are not taught by Sakuma et al.

Respectfully, Sakuma et al. teaches a medicine injection device, based on an artificial or natural root for anchoring in the jaw of a patient. Moreover, Sakuma describes "a medicine injection device or introducing medicine into the body into or at a location under the gingiva" yet, does not teach other anchoring options in an oral cavity, particularly those that are not placed under the gingiva. Claim 1 is now limited to devices using other anchoring options that are not placed under the gingiva, such as dental bridge, partial dentures, full dentures, braces, a molar band, a night guard, and a mouth guard. Such devices include removably and permanently placed devices in the oral cavity, as described in dependent claims 25, 26, 52, 53, 57, 58, 85 and 86 of the instant application.

Respectfully, Sakuma et al. teaches a medicine injection device, "wherein said medicine container is provided with a micro pump". Sakuma et al "further includes a replenishment passage extending from an exterior of said artificial crown to said medicine container". Sakuma et al fails to teach a device and method that "further

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includes a removable component, which houses at least one of said drug reservoir and said power source, said removable component being accessible without an invasive procedure", as described in claims 27, 54, 59 and 87 of the instant application.

Respectfully, Sakuma et al fails to teach a medicine injection device containing an "electronic drug release mechanism" as taught in claims 2, 3, 29, 30, 62, 63, 65, 66, 90, 91, 93 and 94 of the instant application.

Respectfully, Sakuma et al fails to teach a medicine injection device including "a timing device" as described in claims 4, 31, 67 and 95.

Respectfully, Sakuma et al fails to teach a medicine injection device including "controlled drug release in a manner selected from the group consisting of release in accordance with a preprogrammed schedule, release at a controlled rate, delayed release, pulsatile release, chronotherapeutic release, closed-loop release, responsive to a sensor's input, release on demand from a personal extracorporeal system, release in accordance with a schedule specified by a personal extracorporeal system, release on demand from a monitoring center, via a personal extracorporeal system, and release in accordance with a schedule specified by a monitoring center, via a personal extracorporeal system", as taught in claims 18, 45, 81 and 109 of the instant application.

Respectfully, Sakuma et al fails to teach a medicine injection device releasing drugs "in nano-size particles", as described in claims 20, 47, 61, 82, 89 and 110 of the instant application.

***Claim Rejections – 35 USC § 103(a) – Sakuma et al. in view of Taylor et al.***

Claims 19, 46, 64 and 92 have been rejected under 35 USC 103(a) as obvious over Sakuma et al, in view of Taylor et al. (US 5,090,903). As claims 19, 46, 64 and 92 have been canceled, without prejudice, this rejection is moot.

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***Claim Rejections – 35 USC § 103(a) – Sakuma et al. in view of Child***

Claims 17, 44, 80 and 108 have been rejected under 35 USC 103(a) as obvious over Sakuma et al, in view of Child (US 4,252,525).

Respectfully, Child teaches the use of D.C. current to enhance "bactericidal silver ions to be released to the bone tissue and skin tissue approximate the implant". Since the claims before the Examiner are now limited to oral devices that are not implanted in the tissue, Child does not render iontophoresis as been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

***Claim Rejections – 35 USC § 103(a) – Sakuma et al. in view of Pfeiler et al.  
and Voyiazis et al.***

Claims 5-16, 32-43, 68-79 and 96-107 have been rejected under 35 USC 103(a) as obvious over Sakuma et al, in view of Pfeiler et al. (US 5,558,640) and Voyiazis et al. (US 2004/0147906).

Respectfully, Pfeiler et al. teaches the use an "implantable infusion apparatus" and Voyiazis et al. a "dental implant". Since the claims before the Examiner are now limited to oral devices that are not implanted in tissue, Pfeiler et al. and Voyiazis et al. do not constitute prior art rendering sensing and telemetry features as been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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In view of the above amendments and remarks it is respectfully submitted that claims 1-18, 20, 25-45, 47, 52-55, 57-59, 61-63, 65-83, 85-87, 89-91 and 93-110 are now in condition for allowance. A notice of allowance is respectfully solicited.

Respectfully submitted,



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Encl.:  
Request for Continued Examination (RCE)